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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,882	02/24/2005	Andrew I. Poutiatine	DURE-103	4165

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EXAMINER	
BOUCHELLE, LAURA A	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,882	POUTIATINE ET AL.	
	Examiner	Art Unit	
	Laura A. Bouchelle	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☒ Claim(s) *22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 22 is objected to because of the following informalities: Claim 22 recites, "wherein the movable ring is made of ferromagnetic material." The examiner finds no antecedent basis for the movable ring. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, 7, 9, 10, 16, 17, 21, 22, 24, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Theeuwes et al (US 6638263). Theeuwes teaches an implantable flow regulator comprising a movable diversion member 52 and an actuator to move the diversion member between a first position that restricts the flow through the delivery pathway 22 (See Fig. 14) and a second position that allows flow through the pathway (See Fig. 13) (Col. 10, lines 46-67). The diversion member can be biased in the first position to normally restrict flow to the treatment site and supplying power tot actuate the actuator moves the diversion member to the second position (Col. 11, lines 9-15). The delivery conduit 30 has a resilient portion that is deformed by the diversion member such that flow is restricted (Col. 10, lines 50-52). See Fig. 14.

4. Theeuwes discloses that the diversion member 57 can be spheroidal. See Figs. 9 and 10.

5. Theeuwes et al further discloses a diversion pathway 70 from within the first portion between the first portion and the second portion, wherein the diversion tube is a radially offset outlet tube extending from the body (Col. 6,lines 55-59). See Fig. 1.

6. Theeuwes further discloses that the movable member 57 has an axial opening dimensioned to receive the body. See Figs. 9 and 10.

7. Theeuwes discloses that the actuator can be a solenoid that generates a magnetic field when activated (Col. 8, lines 50-54).

8. Theeuwes discloses that the catheter and flow regulator can be of any suitable dimensions that can be varied according to the delivery site and other factors. The inner diameter of the flow delivery conduit can be as small as 0.005 mm meaning that the movable member would have to move much less than a millimeter to occlude the tube (Col. 14, lines 27-35).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 2, 3, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al in view of Urquhart et al (US 4424056). Claim 2 differs from Theeuwes in calling for an accumulation chamber to accumulate a reserve of drug when the diversion member is in the first position. Urquhart teaches a drug delivery system comprising an accumulation

chamber 47 that accumulates drug when the valve 43 is closed allowing flow from the drug delivery source but not to the treatment site (Cool. 8, lines 11-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Theeuwes to include and accumulation chamber as taught by Urquhart so that drug can still flow from the delivery source but not reach the patient while the valve is closed.

11. Claims 3, 26, 28, 29 differ from Theeuwes in calling for the flow through the delivery pathway from the reserve of drug accumulated in the accumulation chamber when the diversion member is in the second position. Urquhart teaches that upon opening of the valve 43 the accumulated drug in the accumulation chamber 47 enters the patient at the specified rate (Col. 8, lines 16-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Theeuwes so that upon opening of the valve the drug flows from the accumulation chamber to the patient as taught by Urquhart so that the drug enters the patient at a specified rate.

12. Claim 27 differs in calling for the flow rate to be substantially constant. Urquhart teaches that the accumulation chamber can be used to adjust the flow rate to the optimal rate and duration parameters (Col. 2, lines 31-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Theeuwes to have constant flow rate out of the accumulation chamber as taught by Urquhart so that the drug can be delivered to the patient at the optimal level.

13. Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al in view of Edwards et al (US 4787406). Claim 5 differs from Theeuwes in calling for the diversion

member to be substantially perpendicular to the direction of flow through the delivery pathway. . Edwards teaches a flow control clamp comprising a diversion member that applies pressure to a deformable conduit in a direction substantially perpendicular to the longitudinal axis of the conduit to restrict flow (Col. 3, lines 19-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Theeuwes so that the diversion member is substantially perpendicular to the direction of flow as taught by Edwards so that the diversion member can restrict flow by providing a force on the deformable conduit.

14. Claims 6, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al in view of Siposs (US 4398908). Claim 6 differs from Theeuwes in calling for the diversion member to have a first end that contacts the conduit and a spring at its second end to dial the diversion member toward the first position. Claims 18 and 19 call for the diversion member to be spring biased toward the first position by a helical spring. Siposs teaches a drug delivery system comprising a diversion member 60 with a first end in contact with a resilient conduit 42 and a spring 62 at its second end to bias the diversion member to the first position wherein the conduit is deformed and flow restricted to allow for the control of the flow when the diversion member is actuated (Col. 4, lines 60-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the diversion member of Theeuwes so that there is a spring at the second end that biases the member toward the first position as taught by Siposs to allow for the control of the flow when the diversion member is actuated.

15. Claims 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes in view of Dorman (US 4657536). Claims 8 and 11 differ from Theeuwes in calling for the delivery to have two overlapping portions. Claim 12 calls for a transverse outlet. Dorman teaches a check valve for a catheter system comprising a first thick walled tube 10 having a central bore 11 wherein the upstream end if open to receive a drug infusion and the down stream end has a transverse port 15 and a portion overlapped by a second flexible tube 16 such that when the infused fluid creates pressure within the tube, the second tube deforms to separate from the downstream end of the first tube and allow fluid to escape from the second tube (Col. 2, lines 35-38, 50-52; Col. 3, lines 10-11; Col. 4, lines 41-48). This configuration allows relief of pressure while preventing backflow into the tubes (Col. 4, lines 48-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Theeuwes to have two overlapping tube portions as taught by Dorman to prevent backflow into the tubes.

16. Claim 13, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes et al in view of Dorman as applied to claims 11 and 12 above, and further in view of Urquhart et al. Claim 13 differs from the teachings of Theeuwes in view of Dorman in calling for an accumulation chamber. Urquhart teaches this limitation as discussed with regards to claim 2 above. For the same reasons, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Theeuwes in view of Dorman to include and accumulation chamber as taught by Urquhart so that drug can still flow from the delivery source but not reach the patient while the valve is closed.

17. Claims 14 and 15, depending from claim 13 call for limitations that are disclosed by Theeuwes as discussed in paragraph 3 of this action.

18. Claims 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes in view of Sunnanvader et al (US 4960259). Claim 20 differs from Theeuwes in calling for the movable member to contact the stop member when it is in the first position. Sunnanvader teaches the use of stop members 10, 10' that are contacted by the movable member 15 to prevent movement of the movable member past the desired amount (Col. 7, lines 27-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Theeuwes to have stop members contacted by the movable member as taught by Sunnanvader to prevent movement beyond the desired amount of the movable member.

1. Claim 23 differs from Theeuwes in calling for the resilient portion to be made of a silicone material. Sunnanvader teaches the use of silicone in the flexible portion 7 of the tube so that it is easily flexible and able to seal off against the inner wall of the opposite side of the tube when it is compressed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the resilient tube of Theeuwes to be made of silicone at taught by Sunnanvader so that the tube can be easily flexible and able to seal off against the inner wall of the opposite side of the tube when it is compressed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle
Examiner
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